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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,219	01/17/2007	Mitsuru Emi	295017US0X PCT	6918
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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER				
REDDIG, PETER J				
ART UNIT		PAPER NUMBER		
1642				
NOTIFICATION DATE		DELIVERY MODE		
02/24/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com

oblonpat@oblon.com

jgardner@oblon.com

Office Action Summary

Application No.

10/590,219

Applicant(s)

EMI ET AL.

Examiner

Peter J. Reddig

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/22)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The Amendment filed December 2, 2009 in response to the Office Action of September 2, 2009 is acknowledged and has been entered. Claims 5, 10-13, 15, and 17 have been amended. Claims 1-4, 6-9 and 13-16 were previously withdrawn.

Amended claims 5 and 10-12 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 5 and 10-12 are now drawn to a method for predicting the postoperative prognosis, in node-negative (nO) breast cancer with no metastasis to a lymph node in operation by measuring expression of a galectin 1 gene, which is distinct from the product claims drawn to the galectin 1 gene correlated with prediction of the postoperative prognosis, in (node-negative)(n0) breast cancer with no metastasis to a lymph node in operation.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 5 and 10-12 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Thus claims 1-16 are withdrawn.

Claims 17-19 are currently being examined.

Rejections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 17-19 remain rejected under 35 U.S.C. 102(b) as being anticipated by US Pat App. Pub. 2003/0087251 (Kurn May 8, 2003) for the reasons set forth in section 12 of the Office Action of September 2, 2009, which are set forth below.

It is noted that the recitation of "gene selected from the following sequences correlated with prediction of the postoperative prognosis, in (node-negative)(n0) breast cancer with no metastasis to a lymph node" in Claims 5 and 10-12 and "A diagnosis kit for the postoperative prognosis of breast cancer" is merely suggestive of an intended use that does not result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art and thus is not given weight for comparison of the claims with the prior art.

US Pat App. Pub. 2003/0087251 teach detection of LGALS1 (galectin-1, see Couraud et al.) in human colon tumor RNA by PCR amplification. See Example 5, Fig. 10, and para. 0443. US Pat App. Pub. 2003/0087251 teaches making microarrays and fiber microarrays with probes for the amplification products of the invention, see paras. 0048-0050, 0125, 0242, and 0276 and claims 120 and 128. US Pat App. Pub. 2003/0087251 teaches kits comprising the microarrays of the invention, para. 0074, 00274-0290.

Applicants argue that the anticipation rejection of Claims 5, 10-12 and 17-19 as being unpatentable in view Kurn is traversed. As described, supra, in the method of present Claim 5, there is a correlation between expression of galectin 1 and breast cancer and between galectin 1 and postoperative prognosis of breast cancer. Kurn does not describe or suggest at least these features of Claim 5 (and the claims depending therefrom). Withdrawal of the obviousness rejection is requested.

Applicants' argument have been considered, but have not been found persuasive because claim 5 and its dependent claims have been withdrawn and a diagnosis kit for the postoperative prognosis of breast cancer" is merely suggestive of an intended use that does not result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art and thus is not given weight for comparison of the claims with the prior art.

3. All other objections and rejections recited in the Office Action of September 2, 2009 are withdrawn.

4. No claims allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Peter J Reddig/

Primary Examiner, Art Unit 1642